UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GENENTECH, INC., Plaintiff, v. THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, Defendant.	Case No.: C 10-2037 PSG **ORDER GRANTING-IN-PART PLAINTIFF'S MOTION FOR PROTECTIVE ORDER** **(Re: Docket No. 303)**

On July 18, 2011, Defendant and Counterclaim-Plaintiff The Trustees of the University of Pennsylvania ("Penn") noticed Plaintiff Genentech, Inc. ("Genentech") of the deposition of those person(s) who Genentech designates to testify on the seven topics discussed below.[1] Despite substantial meet and confer, the parties failed to come to agreement and, on August 19, 2011, Genentech filed the instant motion for a protective order. Genentech moves to prevent Penn from requiring Genentech to prepare a witness on topic 1 of the deposition notice, and to limit various aspects of topics 2-7. These topics are closely related to issues raised in Penn's concurrent motion to compel Genentech to produce documents responsive to Penn's request for production ("RFP")

[1] *See* Docket no. 303-1, Ex. 1. Only the first seven are subject to this motion. Genentech has produced a witness in response to topic 8. *See* Docket no. 303.

nos. 29, 34, 69, and 97, and to respond to Penn's interrogatory nos. 17 and 18. On August 30, 2011, the court heard oral argument on both sets of discovery motions.

Having considered the letter briefs, oral argument, evidence and authority presented by both parties, Genentech's motion for protective order is GRANTED-IN-PART.

I. DISCUSSION

The central question raised by Genentech's motion for protective order is whether the disputed topics fall within or outside the scope of relevant discovery under the court's prior discovery orders, Judge Koh's claim construction, and Fed. R. Civ. P. 26(b)(1) and 30(b)(6). Mirroring its arguments in opposition to Penn's motion to compel, Genentech contends that topic 1 and various aspects of topics 2-7 are overly broad, unduly burdensome, and/or not reasonably calculated to lead to the discovery of admissible evidence. Penn responds that Genentech's motion represents yet another delay in responding to clearly relevant discovery requests.

1. Topic 1 – safe harbor under 35 U.S.C. § 271(e)

Penn seeks to depose Genentech on Topic 1:

> The identity and description of each clinical trial (including open label trials and marketing studies), including Genentech's role in the trial, that (i) was ongoing as of or commenced after November 2006, (ii) was supported or funded by Genentech in whole or in part, and (iii) involved or does involve the administration of Trastuzumab to an individual not diagnosed with metastatic breast cancer.

Genentech objects to Topic 1 on two grounds. First, Genentech argues that the topic is overly broad and improper because it is not limited to breast cell clinical trials, and because those ongoing clinical trials that relate to breast cancer treatment are outside the scope of the '752 patent claim. Second, Genentech argues that discovery on clinical trials is irrelevant based on the exemption of clinical trials under 35 U.S.C. § 271(e)(1).

Penn does not dispute Genentech's arguments but nevertheless responds that section 271(e) does not offer a blanket exemption for all clinical trials, and as such, Genentech must provide a

witness who can identify the relevant clinical trials. Penn contends that this is necessary so that the court, as well as the jury, can determine whether or which trials fall within the safe harbor exemption. Penn also notes in its letter brief that "Genentech need not provide testimony on trials limited to other cancers or DCIS."[2]

Penn is correct. The Supreme Court has construed the section 271(e) exemption to apply "to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the [Food Drug and Cosmetic Act]."[3] Although the Court found "no room in the [patent] statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included" – the research must still be "reasonably related" to the development or submission under the FDCA.[4] There must be some mechanism – other than Genentech's word – for Penn and ultimately the jury to evaluate whether the trials or research being accused fall within the exemption.[5] Genentech shall present a witness who can identify the clinical breast cell trials regarding the administration of Herceptin since adjuvant approval of Herceptin and explain their purpose and nature.[6]

2. Topic 2 – antibodies that compete with Trastuzumab

Penn seeks in Topic 2:

> Genentech's knowledge of any antibodies that bind to a whole or part of domain 4 of the human HER2/neu receptor or show some level of competition with Trastuzumab for binding to the human HER2/neu receptor, and the findings of and dates of experiments that established such binding.

[2] *See* Docket no. 310 at 2, n.2.

[3] *Merck KGAA v. Integra Lifesciences, LTD.*, 545 U.S. 193, 202 (2005).

[4] *Id.*

[5] *See id.* at 200 (quoting jury instruction that '[e]ach of the accused activities must be evaluated separately to determine whether the exemption applies").

[6] *See Amgen, Inc., v. International Trade Comm'n*, 565 F.3d 846, 847, 853 (Fed. Cir. 2009) (holding that safe harbor requires consideration of the exempt status of "each study" for which the question – whether the study was reasonably related to development and submission of information under the FDCA where there is a question of fact – is raised).

Genentech argues that the topic is overbroad and irrelevant because it seeks information on "antibodies that 'show some level of competition with Trastuzumab,'" whereas the '752 patent claims administration of an antibody that competes with the 7.16.4 antibody for binding with p185. Genentech also argues that the topic is "unbounded in time and scope," even though the enablement and written description Penn challenges must be measured as of the date the '752 patent was filed. Because the topic includes antibodies that, by definition, would not infringe the '752 patent, such as those that compete only with Trastuzumab for binding to p185 and not with the 7.16.4 antibody, Genentech argues that the burden outweighs any likely benefit.

Penn responds that topic 2 is directly relevant to Genentech's non-enablement claim, because Genentech specifically alleges that creating antibodies that fall within the scope of the '752 patent requires "undue experimentation." According to Penn, Genentech's response to topic 2 will demonstrate that Genentech itself produced such antibodies without undue experimentation. In addition to the relevance to claim 1 of Penn's infringement contentions, Penn argues that Genentech already has admitted to certain research efforts that also fall within '752 Patent claim 10. As Penn puts it, Genentech should not be permitted to argue lack of enablement and simultaneously withhold relevant discovery regarding its knowledge of antibodies that "show some level of competition." Finally, Penn points out that Genentech may not argue that data on antibodies after the patent's filing date is not relevant since it took the opposite position when Penn had to produce data on antibody experiments to address enablement, and secured a court ruling to that effect.[7]

Genentech may be right that its creation of antibodies that compete with Trastuzumab for binding to the HER2/neu receptor is of no consequence to its non-enablement defense. But that does not render evidence of such work "not reasonably calculated to lead to the discovery of

[7] *See* Docket no. 268.

admissible evidence" on the enablement question. As to time scale, in its June 10 Order and at Genentech's urging, the court did not limit the time frame of Penn's production of data to when the patent was filed, even though Penn argued that later experiments did not matter.[8] If only for consistency and fairness, Genentech should not be permitted to reverse course here. Genentech shall produce a witness on the topic as stated.

3. Topics 3 & 4 – knowledge of "Isolated Tumor Cells"

Topics 3 and 4 relate to the literature on Isolated Tumor Cells ("ITCs") and Genentech's knowledge of whether Herceptin acts or may act on them. Specifically, Topic 3 seeks:

> Genentech's knowledge and awareness, and the knowledge and awareness of its employees and consultants, of the introduction and breast cancer chapters of the International Union Against Cancer TNM Classification of Malignant Tumours Sixth or Seventh Edition, or the AJCC Cancer Staging Manual or Handbook Sixth or Seventh Edition.

Topic 4 seeks testimony on "Genentech's knowledge of information that relates to the question of whether Trastuzumab acts or may act on ITCs."

In its objections to these two topics, Genentech raises the same arguments as in opposition to Penn's motion to compel. It claims that Penn is aiming an end-run around the court's June 16 Order, which limited Penn's discovery to that relating to cells originating in the breast that lack any of the properties of breast cancer. In contrast, topic 4 does not limit its inquiry to breast cells or to cells that overexpress p185. Genentech largely restates its earlier arguments that Penn's reliance on the cancer staging manuals to define the ITCs falls short, since the manuals themselves categorize ITCs as "malignant tumours" and breast cancer cells.[9] In addition, Genentech complains that topic 3 would require Genentech to interview all of its employees, as well as third party consultants, to

[8] *See* Docket no. 268 at 3-4.

[9] Genentech explains that although the UICC reference states that ITCs may not appear to be proliferating, that does not suggest that they are not cancer cells, especially given the court's rejection of proliferation as the test for "cancer" in its claim construction order.

ascertain whether any of them is aware of the manuals – an exercise that it argues creates far greater burden than benefit.

Penn refers the court to its Third Amended Disclosure of Asserted Claims and Infringement Contentions, served on August 9, 2011, in which it alleges inducement and willful infringement based on Herceptin's action specifically on ITCs.[10] Penn claims simply that Genentech's knowledge of the UICC staging manual is relevant to its understanding of whether the accused cells meet the court's construction of p185 overexpressing breast cells. It further emphasizes that because there is a factual dispute between the parties as to whether ITCs are cancer cells within the court's construction, Genentech may not withhold discovery that is reasonably calculated to lead to admissible evidence at trial and assist the trier of fact in determining whether the cells are or are not cancer. Finally, regarding the burden of surveying employees for knowledge of the manuals, Penn reminds Genentech and the court that Genentech secured a similar order requiring Penn to survey its entire breast cancer division, and furthermore, that Genentech should not be allowed later to argue what it did or did not know about ITCs while avoiding discovery on the matter now.

Although Penn added "ITCs" into its infringement contentions only recently, it did so pursuant to the court's order to produce supplemental infringement contentions consistent with the court's claim construction.[11] For all the reasons set forth in the court's companion order, Genentech should present a witness on these ITC-related topics and divulge any non-privileged information relating to whether Trastuzumab acts or may act on ITCs originating in the breast.

4. Topic 5 – knowledge of mammary cells located outside the breast

Penn seeks to depose Genentech on Topic 5:

> Genentech's knowledge of information that relates to the question of whether mammary cells located outside of the breast in humans exist that either (a) fail to

[10] *See* Docket No. 310, Ex. B at Third Revised Ex. A at 4-6.

[11] *See* Docket No. 284.

> show evidence of proliferation or stromal reaction; are single cells; are clusters of cells not more than 0.2mm in greatest dimension, or are non-confluent or nearly confluent clusters of cells not exceeding 200 cells in a single cross-section or sample; or (b) lack one or more of the properties of breast cancer cells as the Court has construed the term.

Part (a) of Topic 5 is derived from the same cancer staging manual(s) discussed above and cited by Penn as the basis for its assertion that ITCs are not cancer cells within the court's construction. Genentech argues that because part (a) refers to "cancer cells," it is outside the scope of the '752 claims and also outside the scope of the court's prior discovery orders. Genentech has proposed to present a witness limited to part (b), relating to cells that originate in the breast, are found outside of the breast, and lack cancer properties as construed by the court.[12] As the court has explained in the companion order, the touchstone of legitimate discovery regarding ITCs is whether a particular ITC meets the requirements of breast cancer cells under Judge Koh's construction. Genentech therefore need only present a witness on topic (b), but may not categorically exclude from this topic any ITC – or any other cell for that matter – that otherwise qualifies.

5. Topics 6 & 7 – persons knowledgeable and documents relating to the above topics

In topics 6 and 7, Penn seeks to depose "the persons at Genentech knowledgeable about the above topics" and "the location and types of documents related to the above topics, and Genentech's efforts to collect such documents." Genentech requests that the court limit the scope of these two topics in accordance with its ruling on the proper scope of topics 1-5.

The court agrees that it is appropriate to limit the scope of these topics in a manner consistent with the scope of the topics previously discussed, and Penn offers no opposition in its papers. Genentech shall tender a witness accordingly.

[12] *See* Docket No. 303, Ex. 3 at 2.

II. CONCLUSION

Consistent with the terms of this order, Genentech shall tender one or more witnesses on the topics discussed without undue delay. In any event, the deposition(s) shall be completed no later than October 16, 2011.

Dated: September 19, 2011

PAUL S. GREWAL
United States Magistrate Judge